THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 146

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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HENRY T. KEUTMANN, PETER SCHOFIELD,
HENRY RODRIQUEZ, BETTY EIPPER
and RICHARD MAINS,
Junior Party,[1]

v.

JAMES P. GILLIGAN and BARRY N. JONES,
Junior Party,[2]

v.

KAZUHIRO OHSUYE, KATSUHIKO KITANO,
SHOJI TANAKA, HISAYUKI MATSUO
and KENSAKU MIZUNO,
Senior Party.[3]

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[1]Application 07/096,447, filed September 15, 1987. Assigned to Johns Hopkins University, Baltimore, Maryland, a corporation of Maryland.

[2]Application 07/086,161, filed August 14, 1987. Assigned to Unigene Laboratories, Inc., Fairfield, New Jersey, a corporation of Delaware.

[3]Application 07/219,375, filed July 15, 1988. Accorded the benefit of Japan SN 62-177184, filed July 17, 1987; and Japan SN 62-306867, filed December 5, 1987. Assigned to

Patent Interference No. 102,700

FINAL HEARING: May 14, 1998

Before CAROFF, METZ, and ELLIS, Administrative Patent Judges.[4]

CAROFF, Administrative Patent Judge.

FINAL DECISION

This interference involves an application of each junior party, Keutmann et al. (Keutmann) and Gilligan et al. (Gilligan), and an application of the senior party, Ohsuye (Ohsuye).

According to the record before us, the involved Keutmann, Gilligan and Ohsuye applications are respectively assigned to

Suntory Limited, Osaka, Japan, a corporation of Japan.

[4]The three-member panel which heard oral argument at final hearing consisted of Administrative Patent Judges (APJ's) Caroff, Sofocleous and Metz. APJ Sofocleous has since retired from government service. Accordingly, the substitution of APJ Ellis has been made for purposes of rendering a final decision. Legal support for the substitution of one panel member for another, without reargument, can be found in In re Bose Corp., 772 F.2d 866, 869-70, 227 USPO 1, 4 (Fed. Cir. 1985).

Johns Hopkins University, Unigene Laboratories, Inc. and Suntory Limited.

The subject matter involved in this interference relates to purified "PAM" protein which, according to Gilligan's principal brief (page 4), is a peptidyl-glycine %-amidating monooxygenase. This enzyme is more particularly defined by the sole count in this interference as follows:

Count 1

A purified PAM protein selected from the group consisting of preproPAM, prePAM, and PAM comprising a membrane spanning domain.

The claims of the parties which correspond to this count are:[5]

Keutmann: Claims 16-20, 31 and 33

Gilligan: Claims 71-92

Ohsuye : Claims 32-33

A Decision on Motions (Paper No. 79) was rendered on July 14, 1993. In that decision, with respect to motions 1(a), 1(b), 1(c), and 2 brought by Ohsuye, it was found that the disclosure of each party is enabling only with respect to the specific source upon which it is focused, i.e., bovine

[5]See Redeclaration (Paper No. 80).

(Keutmann), rat (Gilligan), and frog (Ohsuye). Additionally, it was found that there is no interference-in-fact between the parties with respect to their enabled (i.e., patentable) claims corresponding to the count.

None of the parties to this proceeding contest the holding of no interference-in-fact. Significantly, the party Gilligan also does not dispute the holding that its generic product claims 71-74 (relating to purified PAM protein) are unpatentable in that they go beyond the scope of enablement provided in its specification.

Issues

We are asked to decide the following issues:

I. Whether Gilligan's method claims 76-79, 81-84 and 86-92 are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of a generically enabling disclosure.[6]

II. Whether the same Gilligan method claims are also unpatentable under 35 U.S.C. § 102 or 35 U.S.C. § 103 as being anticipated by, or obvious from, WO 86/02099 (the published PCT equivalent of Gilligan's parent application 06/655,366).[7]

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[6]This issue relates to motion 1(a) which was granted as to Gilligan's claims 71-74, 76-79, 81-84 and 86-92, but denied as to Gilligan's claims 75, 80 and 85.

[7]This issue relates to motion 1(b). The basic underlying issue is the same as that raised in motion 1(a) in that WO 86/02099 is considered to be a reference against all of Gilligan's generic claims 71-74, 76-79, 81-84 and 86-92 if Gilligan's involved and parent applications are found to be nonenabling with respect to those claims. Gilligan does not disagree that WO 86/02099 would be an effective prior art

III. Whether Keutmann's claims 16-20 are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of a generically enabling disclosure.[8]

IV. Disposition of Ohsuye's motion under 37 CFR § 1.656(h) to suppress evidence (Paper No. 136).[9]

Each of the parties has presented a record, submitted exhibits, filed briefs and appeared, through counsel, at final hearing.[10]

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reference under these conditions. Accordingly, we shall view issues I and II as one for purposes of our decision. We note that Gilligan's parent application was filed on September 27, 1984 and WO 86/02099 was published on April 10, 1986; whereas Gilligan's involved application was not filed until August 14, 1987.

[8]This issue relates to motion 1(c) which was granted. We note that Keutmann has two other involved claims directed to a bovine PAM protein (claims 31 and 33) which were added to the interference by way of redeclaration upon motion by Keutmann - see page 6 of the Decision on Motions with regard to unopposed Motion 10.

[9]Gilligan has filed an opposition (Paper No. 141) to the subject motion, and Ohsuye has filed a reply (Paper No. 139).

[10]For each party, its record, exhibits, brief and reply brief will be respectively referred to in our decision, as appropriate, by the abbreviations "R", "X", "B" and "RB", preceded by a letter (K, G or O) representing the name of the party and followed by a pertinent page or exhibit number.

Opinion

I, II.

With respect to the enablement issue, Gilligan's independent method claims 76 (method of purifying a PAM enzyme) and 81 (method of alpha-amidating a peptidyl substrate in the presence of a PAM enzyme) are representative of the generic method claims in dispute and, therefore, are reproduced below for convenient reference:

> 76. A method for purifying an alpha-amidating enzyme capable of catalyzing the conversion of a peptidyl substrate to a peptidyl amide, said peptidyl amide having an amino group in place of the C-terminal amino acid of said substrate, said method comprising the steps of subjecting a composition containing said alpha-amidating enzyme to size exclusion chromatography and to strong anion exchange chromatography.
>
> 81. A method for producing an alpha-amidated product comprising reacting a peptidyl substrate in the presence of an enzymatically effective amount of an enzymatic composition comprising an alpha-amidating enzyme, said enzymatic composition being sufficiently pure in alpha-amidating enzymes to exhibit a specific activity of at least about 25 mU per mg of protein present in said enzymatic composition and said enzymatic composition being sufficiently free of proteolytic impurities to be suitable for use with substrates purified from natural sources or produced by recombinant DNA techniques.

Initially, we note that Ohsuye's arguments alluding to an issue of "separate patentability" (e.g., 0B 25-28, ORB 1-7, 27-29) are out of place since the issue at hand is, rather,

one of enablement. Moreover, Ohsuye's extensive arguments regarding lack of generic enablement for PAM enzyme per se appear to be superfluous inasmuch as lack of enablement for the genus of PAM enzymes, without regard to source or species, is not disputed by Gilligan. However, after a thorough review of the entire record in light of the opposing positions taken by the parties in their briefs, we do agree with Ohsuye that Gilligan's involved and parent application do not provide sufficient enabling support, within the context of the first paragraph of 35 U.S.C. § 112, for the method claims at issue. For reasons which follow, we conclude that Ohsuye's position with regard to the enablement issue more logically conforms with the facts and pertinent case law on the subject than does the position taken by Gilligan.

The fact that the party Gilligan does not dispute that its generic product claims 71-74, directed to purified PAM enzyme without regard to source or species, go beyond the scope of enablement provided in its disclosure is of particular significance. Given this fact, we entirely agree with Ohsuye that logic dictates that Gilligan's disclosure is also nonenabling for the claimed purification and amidation

methods at issue which directly rely upon, and therefore are closely associated with, possession of PAM enzyme in a generic sense (ORB 8-9). In other words, the scope of enablement of those methods is intimately linked to the scope of enablement of the PAM enzyme itself by virtue of the fact that the enzyme is generically recited in the claims as an essential element or feature of each method. Thus, isolation and possession of purified PAM enzyme in a generic sense is a necessary attribute for enablement of the claimed methods. An admitted lack of predictability[11] in identifying a suitable source for obtaining a PAM enzyme of sufficient purity was specifically cited in the Decision on Motions (page 5) as the principal basis for finding lack of enablement with regard to claims generically directed to PAM. We see no reason why this finding does not also apply to Gilligan's generic method claims which relate to purifying and using that enzyme; nor has Gilligan persuaded us of its inapplicability.

The foregoing analysis should not be taken as an attempt

[11]In this regard, we note that motion 1(a), pages 6-7, refers to an amendment filed on June 6, 1986 in Gilligan's parent application which suggests a need to screen large numbers of potential sources of PAM enzyme to identify a source containing sufficient levels of enzyme to be useful.

on our part to formulate a "per se" rule with regard to the enablement of product and method claims. Rather, our finding is based on the facts of this particular case including, inter alia, an admitted lack of predictability in identifying a suitable source of PAM enzyme, the scope of the claims, the scope of enablement provided in Gilligan's disclosure (specification working examples limited to rat sources), and a limited showing by Gilligan regarding the use of one other (bovine) source of PAM (GR 16-20).

Also, we refer to ORB 24-25 for a concise summary of additional reasons why we believe the preponderance of the evidence before us weighs in favor of Ohsuye's position.

Moreover, the case law cited by the parties is more compatible with Ohsuye's position than that of Gilligan. For instance, Ohsuye refers to In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); whereas Gilligan cites In re Herschler, 591 F.2d 693, 200 USPO 711 (CCPA 1979). The distinctions between Wright and Herschler are instructive. First of all, the issue in Herschler related to the written description requirement of 35 U.S.C. § 112 rather than the enablement requirement. Furthermore, as aptly pointed out by

Ohsuye (ORB-26), Herschler involved a well known, well defined, class of compounds (steroids), unlike the generic class of PAM enzymes recited in the method claims here at issue. The disclosure of Herschler also exemplified a diversity of drugs, much broader than the diversity of steroid compounds, shown to be potentiated by DMSO

as required by the method claimed in Herschler. No comparable diversity of PAM enzymes is exemplified in Gilligan's disclosure. Moreover, the issues and facts in Wright are more in tune with those before us. As here, Wright involved an issue of whether the scope of product and method claims bears a reasonable correlation to the scope of enablement provided by the specification. In deciding that issue, the court in Wright did not distinguish between the product and method claims in affirming a 35 U.S.C. § 112 rejection against all the claims for lack of enablement. Given the breadth of the claims and an element of unpredictability in the art, the court found, as we do here, that for one skilled in the art to practice the full scope of the claimed invention according to the teachings of the specification would involve undue experimentation.

Finally, we note that Gilligan (GRB-18) also relies on a statement in Fiers v. Sugano, 984, F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) to the effect that conception of a process for making a substance, without a structural definition of that substance, "can at most constitute a conception of the substance claimed as a process." In our

opinion, that statement in Fiers is not dispositive with regard to the issue before us. First of all, the statement is mere dicta not applicable here since the count at issue in Fiers was directed to a product not a process. Further, the qualifying expression "at most" makes it clear that the court was not making a categorical statement that all such processes would necessarily pass muster after undergoing an enablement analysis based on the facts of a particular case.

For the foregoing reasons, we find that Gilligan's method claims 76-79, 81-84 and 86-92 are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement.

III.

Keutmann argues that consistent treatment requires that all of Keutmann's claims be found patentable under the first paragraph of 35 U.S.C. § 112 if and only if all of Gilligan's claims are found to be patentable under 35 U.S.C. § 112 (KB-4). This is the only basis for relief argued by Keutmann. Accordingly, since we have found all of Gilligan's generic claims to be unpatentable, we also find all of Keutmann's generic claims to be unpatentable on the same basis.

IV.

Ohsuye's motion to suppress is dismissed as moot since we have found that Gilligan does not prevail on the substantive issues before us even when considering all of the evidence adduced by Gilligan in its entirety. Therefore, we find it unnecessary to consider the specific objections raised by Ohsuye in its motion.

Judgment

For all of the foregoing reasons, and in view of the uncontested finding of no interference-in-fact, judgment is hereby entered as follows:

The party Keutmann is entitled to a patent containing its involved claims 31 and 33, but is not entitled to a patent containing its involved claims 16-20.[12]

The party Gilligan is entitled to a patent containing its claims 75, 80 and 85, but is not entitled to a patent containing its involved claims 71-74, 76-79, 81-84, and 86-92.

[12]We note that the party Keutmann's involved application also contains pending claims 1-15 and 21-28 which have been indicated as being allowable in the examiner's initial memorandum (Form PTO-850). Since those claims have been designated as not corresponding to the count, they are not involved in this interference proceeding.

The party Ohsuye is entitled to a patent containing all its involved claims 32-33.

MARC L. CAROFF Administrative Patent Judge	)	
ANDREW H. METZ Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JOAN ELLIS Administrative Patent Judge	)	

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